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# TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No. 12.018011

In Re Application Of: **Hung**

| Application No. | Filing Date | Examiner | Customer No. | Group Art Unit | Confirmation No. |
|---|---|---|---|---|---|
| 09/912,499 | July 26, 2001 | Kevin Sirmons | 0000 38732 | 3763 | 6261 |

Invention: **Methods & Devices for Diagnosis of Precancer and Cancer in Breast Milk Ducts**

COMMISSIONER FOR PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

**October 12, 2005**

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Dated: 2/15/2006

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

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Attorney's Docket No. 12.018011 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|---|---|---|---|
| APPELLANT : | HUNG, DAVID | ART UNIT : | 3763 |
| SERIAL NO. : | 09/912,499 | EXAMINER : | KEVIN C. SIRMONS. |
| FILED : | JULY 26, 2001 | | |

TITLE : METHODS AND DEVICES FOR DIAGNOSIS OF PRECANCER AND CANCER IN BREAST MILK DUCTS



February 15, 2006

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**APPEAL BRIEF**

Sir:

In accordance with 37 CFR §41.37 this Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed October 12, 2005. Please charge the amount of $500 to cover the required fee for filing this Appeal Brief as set forth under 37 CFR §41.37(a)(2) and 37 CFR §41.20(b)(2) to Deposit Account No. 502855. Also, please charge any additional fees or credit any overpayments to Deposit Account No. 502855.

**Real Party in Interest.**

The real party in interest in this appeal is Cytyc Corporation, Inc., the assignee of the above-referenced patent application.

**Related Appeals and Interferences.**

There are no related appeals and/or interferences involving this application or its subject matter.

**Status of Claims.**

Claims 1-8, 10-13, 26, and 27 are the subject of this appeal. Claims 1-6, 12 and 13 have been rejected under 35 USC §102(b) as being anticipated by United States Patent No. 5,623,942 to Pestes *et al.* Claims 7-8, 10, 26, and 27 have been rejected under 35 USC §103(a) as being unpatentable over Unites States Patent No. 5,623,942 to Pestes *et al.* in view of United States Patent No. 4,616,656 to Nicholson *et al.* Claim 11 has been rejected under 35 USC §103(a) as being unpatentable over Unites States Patent No. 5,623,942 to Pestes *et al.* in view of United States Patent No. 4,947, 842 to Marchosky *et al.* The pending claims under appeal appear in Appendix A. No other claims are pending. Claims 9 and 14-25 have been cancelled.

**Status of Amendments.**

All of Appellant's amendments have been entered.

**Summary of the Claimed Subject Matter.**

The Appellants' pending claims of the present invention are directed to a device for retrieving and analyzing a sample of breast duct fluid (including ductal epithelial cells and other ductal contents) for the purpose of diagnosing a breast condition, including the conditions of cancer or precancer. Appellants' device for collecting breast duct fluid from within a breast duct is comprised of a probe having a diameter sized to access a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis, and wherein said probe is free of an opening through which a fluid from an external source can be introduced into said probe and pass through said probe into the

duct when said probe is positioned within the breast duct, and wherein said probe is rigid before entry into the breast duct, and flexible upon resistance in the duct. (see, e.g. page 3, line 27 – page 4, line 13 of Appellants' specification).

**Grounds of Rejection to be Reviewed on Appeal.**

Claims 1-6, 12 and 13 have been rejected under 35 USC §102(b) as being anticipated by United States Patent No. 5,623,942 to Pestes *et al.* Claims 7-8, 10, 26, and 27 have been rejected under 35 USC §103(a) as being obvious over Unites States Patent No. 5,623,942 to Pestes *et al.* in view of United States Patent No. 4,616,656 to Nicholson *et al.* Claim 11 has been rejected under 35 USC §103(a) as being obvious over Unites States Patent No. 5,623,942 to Pestes *et al.* in view of United States Patent No. 4,947, 842 to Marchosky *et al.*

**ARGUMENT**

## A. INDEPENDENT CLAIM 1 IS PATENTABLE OVER PESTES *ET AL.*

The Examiner states that independent claim 1 is unpatentable under 35 U.S.C. § 102(b) in view of Unites States Patent No. 5,623,942 to Pestes *et al.* The Appellant respectfully traverses the rejection for the following reasons.

In the Final Office Action dated August 15, 2005, the Examiner, asserted that the Patent to Pestes *et al.* discloses a flexible probe having a diameter sized to access a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis. The Examiner declares that the probe "...is rigid before entry into the breast duct, and flexible upon resistance into the duct..." (see page 2 of the

Final Office Action). The Applicant respectfully disagrees.

As mentioned in the Appellant's response filed May 18, 2005, the Patent to Pestes *et al.* does not contemplate a method or device that is composed of a material that is rigid in one state and flexible upon entry into a breast duct. Nowhere in Pestes *et al.* can the examiner point to such a statement or teaching. In the Office Action of February 22, 2005, the Examiner points to certain paragraphs in the body of Pestes *et al.* (col. 2, lines 16-25 and 32-40) as support for such a statement, however, no such description exists. In fact, as specifically stated in Pestes *et al.*, (see column 2 lines 32-33) the preferred material for the shaft of the probe is fiberglass. Fiberglass is highly non-flexible and certainly would not be ductile upon resistance to a duct.

In response to the Appellant's arguments, the Examiner replies that "...all materials disclosed in Pestes *et al* and in applicant's specification can have varying degrees of rigidity and flexibility. Pestes *et al* clearly discloses that his device it [sic] both flexible (ductile) and rigid (stiff). Applicant has failed to indicate to what degree of rigidity and what degree of flexibility. Therefore, the prior art can be anywhere in between." (see page 5, first full paragraph of Final Office Action). The Appellant disagrees.

The question is not whether or not the materials disclosed in Pestes *et al.* have differing degrees of flexibility or rigidity, the question is whether or not the functional features of the disclosed invention are also disclosed in the prior art cited by the Examiner. The Board of Patent Appeals has stated that if an invention being claimed includes functional features, then to be anticipating, the prior art must also disclose those functional features. (*Ex parte* Gunn, 19 USPQ 226, 227 (Bd. Pat. App.1932) The device of the present invention is comprised of a probe of a

certain diameter for penetration of a breast duct which is rigid before entry into the breast duct and flexible upon resistance in the duct. Thus, one functional feature of the present invention requires that the probe be of sufficient rigidity to enter through the sphincter of a breast duct, but flexible enough that the body of the probe will bend when it encounters resistance within the breast duct (e.g., reaches a branch in the ductal pathway). In contrast, the device described in Pestes *et al.* is comprised of fiberglass filled nylon in such a ratio as to "...provide sufficient ductility that the shaft will not break in use and still be stiff enough to prevent it from being bent during its intended use..." (emphasis added)(see column 2, lines 32-35) Clearly, not all of the functional features of the present invention are disclosed in Pestes *et al.* In fact, the Appellant would argue that the functional features of Pestes *et al* teaches away from the functional features of the present invention. Pestes *et al.* specifically describes a device with has a shaft that is stiff enough that it will not bend during its intended use, whereas the present invention specifically requires that the probe have enough flexibility which will allow it to bend when it encounters resistance within a breast duct. The Examiner argues that the Appellant relies on features (i.e., materials) that are not recited into the claims. The Appellant disagrees. Notwithstanding the materials used, the Appellant has described a probe for use in breast ducts which has a specific functional feature of being bendable once inserted within a breast duct. The Examiner has failed to show that Pestes *et al.* discloses that exact functional feature. In fact, Pestes *et al.* teaches away from the feature described in the claim 1. Since Pestes *et al.* does not disclose all of the limitations of the present invention, Pestes *et al.* cannot anticipate independent claim 1. For these reasons, Appellant respectfully requests the withdrawal of the rejection of claim 1 as well as dependant claims 2-6, 12 and 13 under 35 U.S.C. §103(a) in view

of the Pestes *et al.* disclosure.

## B. DEPENDENT CLAIM 6 IS PATENTABLE OVER PESTES *ET AL.*

Dependent claim 6 (like all of the dependent claims) is allowable over the prior art because it is dependent on independent claim 1, and thus contain all the limitations of this independent claim. The Examiner has rejected dependent claim 6 as being unpatentable under 35 U.S.C. § 102(b) in view of Unites States Patent No. 5,623,942 to Pestes *et al.* Dependent claim 6 recites a device as in claim 1, wherein the distal portion of the probe comprises a surface having molecules affixed that bind an agent in the ductal fluid it contacts. The Examiner has not cited any prior art which teaches or suggests a flexible probe having a diameter sized to access a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis, wherein the distal portion of the probe comprises a surface having molecules affixed that bind an agent in the ductal fluid it contacts. Pestes *et al.* does not teach or suggest a surface having molecules affixed that bind an agent in the ductal fluid. For these reasons, Appellant respectfully requests the withdrawal of the rejection of claim 6 under 35 U.S.C. §102(b).

## C. DEPENDENT CLAIM 13 IS PATENTABLE OVER PESTES *ET AL.*

Dependent claim 13 (like all of the dependent claims) is allowable over the prior art because it is dependent on independent claim 1, and thus contain all the limitations of this independent claim. The Examiner has rejected dependent claim 13 as being unpatentable under 35 U.S.C. § 102(b) in view of Unites States Patent No. 5,623,942 to Pestes *et al.* Dependent claim 13 recites a

device as in claim 1, wherein the probe comprises a shape memory material. The Examiner has not cited any prior art which teaches or suggests a flexible probe having a diameter sized to access a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis, wherein the probe comprises a shape memory material. Pestes *et al.* does not teach or suggest a probe comprises a shape memory material. The materials disclosed in Pestes *et al.* are nylon and fiberglass, neither of which are shape memory materials. For these reasons, Appellant respectfully requests the withdrawal of the rejection of claim 13 under 35 U.S.C. §102(b).

## D. DEPENDENT CLAIMS 7-8, AND 10 ARE PATENTABLE OVER PESTES *ET AL.* IN VIEW OF NICHOLSON *ET AL.*

Claims 7-8, and 10 have been rejected under 35 USC §103(a) as being obvious over Unites States Patent No. 5,623,942 to Pestes *et al.* in view of United States Patent No. 4,616,656 to Nicholson *et al.* Appellant respectfully traverses the rejection for the following reasons.

### 1. Neither Pestes *et al.* nor Nicholson *et al.* Teach or Suggest Methods for Measuring the Quality of Ductal Fluid

As noted in M.P.E.P. § 2143.03, to establish the obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. The method recited in Appellant's dependent claims 7-8 and 10 include a means to measure the quality of the ductal fluid *in situ* wherein the quality comprises an indicia selected from the group consisting of cell size, cell density,

nuclear size, nucleoli size, chromatin coarseness, or the indicia is a marker.

As acknowledged by the Examiner at page 3 of the Office Action dated September 8, 2004, Pestes *et al.* fails to disclose a means (marker/indicia) to measure a quality of the ductal fluid *in situ*. The Examiner then proceeds to argue that Nicholson *et al.* discloses a means (marker/indicia) to measure a quality of the ductal fluid *in situ* as evidenced by column 4 lines 12-17 of the specification. Therefore, the Examiner argues, it would have been obvious to one of ordinary skill in the art at the time the invention was made to"...modify the distal portion of Pestes with the means to measure a quality of the ductal fluid as taught by Nicholson for providing markings to indicate the depth of the device distal end when anchored. Note: applicant indicates that his quality/means can comprise a marker (page 4, line (8)." (see page 4 of the Office Action dated September 8, 2004). The Appellant respectfully disagrees.

Nicholson *et al.* discloses a probe sheath and probe wire to locate presymptomatic breast lesions. The Examiner argues that Nicholson *et al.* discloses a means (marker/indicia) to measure a quality of the ductal fluid *in situ* because the graduations on the proximal end of the probe wire are "markers". First, the Examiner has apparently misconstrued the Appellant's use of the term "marker". In the Appellant's application, the term "marker" is clearly defined as referring to biological indicia not physical indicia. In one example on page 10, last paragraph of the Appellant's specification, the term is explicitly defined:

> The agent or marker sought in the ductal fluid can be, e.g. a molecule such as an antibody, a peptide, a polypeptide, a nucleic acid, a polynucleotide, a small organic molecule, a macromolecule, a polymer, a carbohydrate, or a lipid. In general any marker characteristic of ductal precancer or cancer can be used, provided it is retrievable by the probe.

This definition is corroborated by the Appellant's use of other examples of indicia used for determining the quality of ductal fluid such as cell size, cell density, nuclear size, nucleoli size, and chromatin coarseness (see dependent claim 8 and page 4, lines 4-6 of the specification).

Second, the Examiner apparently misconstrues the term "quality". The term "quality" is defined as a peculiar and essential character or an inherent feature (see Merriam-Webster Dictionary 2005 edition). As mentioned previously, the Examiner argues that Nicholson *et al.* discloses a means to measure a quality of the ductal fluid *in situ* because of the graduations on the proximal end of a probe wire. Graduations on the end of the probe wire used in Nicholson *et al.* are not used to determine the quality of a fluid. The graduations on the wire are explicitly used to indicate the depth of the probe wire's distal end when anchored. Depth is a measurement of amount. Such a measurement is a quantitative measure (measuring the amount or quantity) not a qualitative measurement. There is simply no suggestion or teaching in Nicholson *et al.* of a means for measuring any qualitative indicia.

Lastly, there is no teaching or suggestion in Nicholson *et al.* of a means to detect any indicia in ductal fluid. There is no mention anywhere in Nicholson *et al.* of breast ducts or ductal fluid.

Thus, Pestes *et al.* fails to disclose a means (marker/indicia) to measure a quality of the ductal fluid *in situ* and Nicholson *et al.* fails to overcome the shortcomings of Pestes *et al.* Nicholson *et al.* simply does not teach or disclose a means for determining the quality of ductal fluid as described in dependent claim 7. Nicholson *et al.* also does not teach or disclose a means for determining the quality of ductal fluid when the quality comprises an indicia selected from the group consisting of cell size, cell density, nuclear size, nucleoli size, and chromatin coarseness as described in dependent

claim 8. Lastly, Nicholson *et al.* does not teach or disclose a means for determining the quality of ductal fluid when the quality comprises a marker as taught by Appellant's specification.

For these reasons, Appellant respectfully requests the withdrawal of the rejection of claims 7-8 and 10 under 35 U.S.C. §103(a) in view of the Nicholson *et al.* disclosure.

## E. DEPENDENT CLAIMS 26 and 27 ARE PATENTABLE OVER PESTES *ET AL.*

Dependent claims 26 and 27 (like all of the dependent claims) are allowable over the prior art because it is dependent on independent claim 1, and thus contain all the limitations of this independent claim. A rejection of Claims 26 and 27 was made by the Examiner without making specific reference to the cited art. Although the rejection of claims 26 and 27 is included under the section of rejections under 35 USC §103(a) as being obvious over Unites States Patent No. 5,623,942 to Pestes *et al.* in view of Nicholson *et al.*, it is apparent to the Appellant that the Examiner is basing his rejection of claims 26 and 27 solely under 35 USC §103(a) as being obvious in view of Pestes *et al.* If this is not true, the Appellant requests clarification from the Examiner.

The basis for the Appellant's assumption is that Nicholson *et al.* does not contain any teachings or suggestion of the dimension or diameter of a probe that is sized to access a breast duct nor does the Examiner attempt to argue that Nicholson *et al.* contains such a teaching. Instead, the Examiner argues that it would have been obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to have various diameters of the probe found in Pestes *et al.* Appellant respectfully traverses the rejection for the following reasons.

The Examiner argues that Pestes *et al.* discloses a device for collecting breast fluid with a

diameter of 0.08cm which is substantially the same as the claimed invention except that the probe has a diameter between 0.008 cm to about 0.045cm. The Examiner then goes on to argue that a change in size is generally recognized as being within the level of ordinary skill in the art unless the Appellant can explain why the difference in diameters solves a stated problem in the art or is for any particular purpose (see February 22, 2005 Office Action page 4). The Appellant would argue that the differences in diameter solve a particular problem i.e., that the probe of Pestes *et al.* is sized to fit from the male urethra while the probe of the present invention is sized to fit into a female breast duct. The probe of Pestes *et al.* is sized from approximately 0.100 inches (0.254 cm) in diameter at the handle and tapers too approximately 0.035 inches (0.089cm) in diameter at the distal tip. The probe of the present invention has a shaft in the range of 0.008cm to about 0.040 cm in diameter with a preferred range of 0.012cm to about 0.025cm. Although the probe of the present invention may also be tapered, the change in diameter runs from a minimum of 0.008 to a maximum of 0.1cm. The probe of Pestes *et al.* starts at a minimum diameter of 0.89cm and runs to a maximum of 0.254cm. It should also be noted that, although the shaft of the probe described in Pestes *et al.* tapers to 0.089cm, the actual diameter of the distal tip of the device is actually much larger due to the fiber tip which surrounds the distal end of the device (see Figure 3 of Pestes *et al.*). Therefore, the overall diameter of the probe described in Pestes *et al.* would make it impractical to be used as a device to retrieve fluid from a breast duct. Attempting to insert a probe the diameter taught in Pestes *et al.* may be successful for the very tip of the probe (assuming no fiber tip), however, as the probe is inserted deeper into the ductal canal, the increased diameter of the probe (to a maximum of 0.254cm) would cause considerable pain to the patient as well as potentially causing damage to the

ducts themselves. Aside from differences in diameter, the probe described in Pestes *et al.* solves a different medical problem then the probe of the present invention.

In the area of medical technologies for example, courts have held "Combining devices that have a short guide wire lumen, but are not used in dilatation or coronary dilatation, with PTA and PTCA [Percutaneous Transluminal Coronary Angioplasty] devices that have a long guide wire lumen, **would not have been obvious to one of ordinary skill because they would not have been particularly pertinent to the particular problem with which [the inventor] was concerned** (emphasis added)." *Schneider (Europe) AG v. SciMed Life Systems Inc.*, 852 F. Supp. 813, 853 (D. Minn. 1994), *aff'd*, 60 F.3d 839 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 990 (1995).

Appellant respectfully traverses the outstanding rejection to claims 26 and 27 in view of Pestes *et al.* because the disclosure in the Pestes *et al.* reference is in a different field of medicine as the subject matter in claims 26 and 27 and further because the medical problem pertinent to the Pestes *et al.* disclosure is not reasonably pertinent to the particular problem with which the inventor was concerned. In particular, an analysis of Pestes *et al.* shows that it is in the field of obtaining cells from a male urethra while the medical problem pertinent to the present invention is the collection of fluid which contains a small amount of cellular material from a female breast duct.

The fact that the Pestes *et al.* disclosure is directed to completely different problems is illustrated for example by considering the different anatomical regions in which these procedures are performed, the different tissues collected by these procedures and the different structural properties of the catheters used in these procedures. For example, it is not correct to assume that the issues relating to collecting cells from a male urethra are reasonably pertinent to the issues relating to

collecting fluid from a female breast duct. This is illustrated for example by a comparison of the internal diameter of probes used, the different compositions of the probes, and the different materials collected. This comparison shows not only that male urology and female ductology are different fields of medicine but also that the particular problems associated with collecting samples from the patients are different in these two fields. In view of these clear differences in both the field of medicine and the particular problem with which the inventor was concerned, the Appellant respectfully request the withdrawal of the rejection of claims 26 and 27 under 35 U.S.C. §103(a) in view of Pestes *et al.*.

As noted above, because the problems concerning artisans relying on the disclosure in Pestes *et al.* are not pertinent to the problems concerning the present disclosure, artisans lack the required motivation to combine them in a manner that renders the claimed invention obvious. *Schneider* 60 F.3d 839. In addition, because it is in a different field of medicine and is directed to a different problem than the claimed subject matter, the Pestes *et al.* reference also fails to provide a teaching or motivation to generate methods having the combination of elements recited in independent claim 26 and 27. For these reasons, Appellant respectfully requests the withdrawal of the rejection of claims 26 and 27 under 35 U.S.C. §103(a) in view of Pestes *et al.*

## F. DEPENDENT CLAIM 11 IS PATENTABLE OVER MARCHOSKY *ET AL.*

Dependent claim 11 (like all of the dependent claims) is allowable over the prior art because it is dependent on independent claim 1, and thus contain all the limitations of this independent claim. Claim 11 has been rejected under 35 USC §103(a) as being obvious over Unites States Patent

No. 5,623,942 to Pestes *et al.* in view of United States Patent No. 4,947,842 to Marchosky *et al.* Appellant respectfully traverses the rejection for the following reasons.

The Marchosky *et al.* reference is cited by the Examiner merely for its teaching that an anesthetic may be placed on the exterior of a probe for treating tumors interstitially. Marchosky *et al.* does not teach or suggest the use of a coating of an anesthetic on the exterior of a probe for collecting breast duct fluid from within a breast duct in order to detect breast cancer or precancer as recited in the claims.

A new combination of elements can be patented "whether it be composed of elements all new, partly new or all old." *Rosmount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546, 221 USPQ 1, 7 (CAFC 1984). The Court of Appeals for the Federal Circuit has forcefully stated that a claim rejection must provide a specific motivation in the art for combining elements from cited art in order to establish obviousness of a new combination.

> "[C]ase law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. ... Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. ... [Evidence of a suggestion, teaching, or motivation to combine] must be clear and particular. ... Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.' ... [A] reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the [cited] references teach or suggest their combination ... to yield the claimed invention," and a conclusion of obviousness based on such an analysis "as a matter of law, cannot stand." *In re Dembiczak*, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618

(Fed. Cir. 1999), emphasis added.

*Dembiczak* involved patent claims to "a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern." *Dembiczak*, 996, 1616. The prior art cited by the Board included: a book describing how to teach children to make a "Crepe Paper Jack-O-Lantern;" a book describing a method of making a "paper bag pumpkin" by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint; a U.S. Patent describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material; design patents issued to Dembiczak; and prior art "conventional" plastic lawn or trash bags. The Federal Circuit held that the claimed pumpkin-style trash bag was not obvious because there was no clear, particular motivation to combine the cited references.

This holding of *Dembiczak* that evidence of motivation to combine must be clear and particular to establish obviousness has been emphasized over and over again by the Federal Circuit since *Dembiczak* was decided. It was strongly reemphasized in *Ruiz v. A.B. Chance Co.*, 57 USPQ2d 1161 (Fed. Cir. 2000):

> In order to prevent a hindsight-based obviousness analysis, we have clearly established that the relevant inquiry for determining the scope and content of the prior art is whether there is a reason, suggestion, or motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to combine the references. See, e.g., In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("[T]he Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."); In re Dembiczak, 175

> F.3d at 999, 50 USPQ2d at 1617 ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."). "Determining whether there is a suggestion or motivation to modify a prior art reference is one aspect of determining the scope and content of the prior art, a fact question subsidiary to the ultimate conclusion of obviousness." Sibia Neurosciences, Inc. v. Cadus Pharma. Corp., 225 F.3d 1349, 1356, 55 USPQ2d 1927, 1931 (Fed. Cir. 2000); Tec Air, Inc. v. Denso Mfg., Inc., 192 F.3d 1353, 1359, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) (stating that the factual underpinnings of obviousness include whether a reference provides a motivation to combine its teachings with those of another reference). ... there is "a general rule that combination claims can consist of combinations of old elements as well as new elements," Clearstream Wastewater Sys. v. Hydro-Action, Inc., 206 F.3d 1440, 1446, 54 USPQ2d 1185, 1189-90 (Fed. Cir. 2000), "[t]he notion . . . that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, § 103." Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1575, 1 USPQ2d 1593, 1603 (Fed. Cir. 1987); Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997) ("It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements."). *Ruiz* at 1167

The motivation cited in the Office Action for the proposed combination is as follows:

> "It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Pestes with the coating as taught by Marchosky to relieve pain in the treatment of tumors particularly in the area of the breast." February 22, 2005 Office Action at page 4, third paragraph.

This statement does not provide the clear, particular suggestion in the art for making the

specific claimed combination as is required under *In re Dembiczak*. The claims here are no more obvious than those at issue in *Dembiczak*. No clear, particular suggestion or motivation in the prior art to make the specific combination of "a probe having a diameter sized to access a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis, and wherein said probe is free of an opening through which a fluid from an external source can be introduced into said probe and pass through said probe into the duct when said probe is positioned within the breast duct, and wherein said probe is rigid before entry into the breast duct, and flexible upon resistance in the duct" recited in claim 1 with "a coating of an anesthetic on the exterior of the probe" required by claim 11 has been provided. *Prima facie* obviousness has not been established under such conditions. Furthermore, Pestes *et al.* and Marchosky *et al.* cannot properly be combined. Neither Pestes *et al.* nor Marchosky *et al.* teach or suggest a device that can be used for the retrieval of fluid from a breast duct as recited in the claims. Pestes *et al.* teaches a probe for collecting cells from a male urethra and Marchosky *et al.* teaches the use of an apparatus for treating tumors interstitially. No where in either Pestes *et al.* or Marchosky *et al.* is there any teaching or suggestion to obtain fluid from a breast duct. Therefore, the obviousness rejection is based on hindsight from these disparate references to provide random elements of the claims. There is no clear, particular motivation in the references to reach the claimed invention. Consequently, Marchosky *et al.* fails to overcome the deficiencies of the Pestes *et al.* reference. Because a combination of the Pestes *et al.* and Marchosky *et al.* fail to generate the invention recited in claim 11, the standard for obviousness under 35 USC 103(a) cannot be met. For this reason, Appellant respectfully requests the withdrawal of the rejection of claim 11

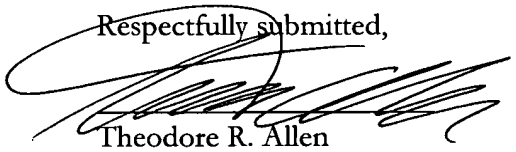
under 35 U.S.C. §103(a) as being obvious over Unites States Patent No. 5,623,942 to Pestes *et al.* in view of United States Patent No. 4,947,842 to Marchosky *et al.*

## CONCLUSION

In light of the above arguments, Appellant respectfully submits that the cited references do not anticipate nor render obvious the claimed invention. More specifically, Appellants' claims recite novel physical features which patentably distinguish over any and all references under 35 U.S.C. §§ 102 and 103. As a result, a decision by the Board of Patent Appeals and Interferences reversing the Examiner and directing allowance of the pending claims in the subject application is respectfully solicited.

Customer No. 0000 38732

Respectfully submitted,



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## APPENDIX A: PENDING CLAIMS

1 A device for collecting breast duct fluid from within a breast duct in order to detect breast cancer or precancer comprising:

a probe having a diameter sized to access a breast duct and a distal portion being capable of contacting an interior lumen of a breast duct and retrieving a sample of the breast duct fluid from within the duct for analysis, and wherein said probe is free of an opening through which a fluid from an external source can be introduced into said probe and pass through said probe into the duct when said probe is positioned within the breast duct, and wherein said probe is rigid before entry into the breast duct, and flexible upon resistance in the duct.

2 A device as in claim 1, wherein the distal portion comprises an absorbant material that can absorb the breast duct fluid.

3 A device as in claim 1, wherein the distal portion comprises a collection portion that can collect the breast duct fluid it contacts.

4 A device as in claim 3, wherein the collection portion is tubular.

5 A device as in claim 3, wherein the collection portion extends some distance from the probe.

6 A device as in claim 1, wherein the distal portion comprises a surface having

molecules affixed that bind an agent in the ductal fluid it contacts.

7 A device as in claim 1, wherein the distal portion comprises a means to measure a quality of the ductal fluid *in situ*.

8 A device as in claim 7, wherein the quality comprises an indicia selected from the group consisting of cell size, cell density, nuclear size, nucleoli size, and chromatin coarseness.

10 A device as in claim 7, wherein the quality comprises a marker.

11 A device as in claim 1, further comprising a coating of an anesthetic on the exterior of the probe.

12 A device as in claim 1, wherein the probe is rigid before entry into the breast duct, and flexible upon resistance in the duct.

13 A device as in claim 1, wherein the probe comprises a shape memory material.

26 A device as in claim 1, wherein said diameter of said probe is between about 0.008 cm and about 0.040 cm.

27 A device as in claim 1, wherein said diameter of said probe is between about 0.012 cm and about 0.025 cm.

## APPENDIX B: EVIDENCE

**NONE**

## APPENDIX C: RELATED PROCEEDINGS

NONE